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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,021	02/09/2004	Ramez Emile Necola Shehada	064693-0103	9078

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EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,021	Applicant(s) SHEHADA, RAMEZ EMILE NECOLA	
	Examiner Melanie J. Hand	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/22/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1 and 3-15 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims.

With respect to applicant's argument regarding the rejection of claims 1 and 4-10 under 35 U.S.C. 102 and the rejection of claims 11-15 under 35 U.S.C. 103, Examiner agrees and has withdrawn the rejection under 35 U.S.C. 102 and has restated the rejections of claims 11-15 to reflect the new grounds of rejection of claim 1 in view of a different interpretation of a previously applied prior art reference.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 22, 2006 was filed after the mailing date of the Application on February 9, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiddian-Green (U.S. Patent No. 6,334,064).

With respect to **Claim 1**: Fiddian-Green teaches a tonometric catheter sensing apparatus comprising implantable surgical drain 20. Balloon-like membrane 36 serves as a contact optimizer for draining fluid and sensing at least one physiological property of a tissue in a patient's body. Drain 20 is comprised of elongated conduit 22 configured to be implanted in a patient's body to drain fluid from a tissue of the body, the elongated conduit having a first and second surface on an outer side of the elongated conduit. A first sensing element 42 is positioned at the first surface of the elongated conduit and is configured to sense a physiological property of said tissue. Membrane 36 is configured to optimize contact between the first sensing element and the tissue. (Fig. 1) (Col. 5, lines 6-8,16)

Balloon-like membrane 36 (first inflatable compartment) is fitted over the closed end of elongated tubing 22 and is thus not positioned between the first and second surfaces of said conduit. However the conventional balloon catheter is well known in the art and comprises at least one balloon that is disposed inside a lumen and subsequently inflated to anchor the catheter in place. Therefore it would be obvious to one of ordinary skill in the art to add an additional inflatable compartment in the form of a balloon that is positioned between said first and second surfaces to enhance the securement of the catheter in place.

With respect to **Claim 3**: Balloon membrane 36 is configured to fit within conduit 22 and is held therein until positioned adjacent tissue and inflated.

With respect to **Claim 4**: Fiddian Green teaches a first sensing element enclosed by balloon 36 (Col. 5, lines 16,17,40-42) and as can best be seen from Fig. 1, balloon 36 and sensors 42 are located at approximately the same position along tubing 22.

With respect to **Claims 5 and 6**: Fiddian-Green teaches that a first sensing element detects properties indicative of pH and/or temperature. Each of sensors 42 (on of which is a second sensing element) can measure the partial pressures of hydrogen, oxygen, or carbon dioxide in the tissue environment, thus the second sensing element is capable of being configured to sense a different physiological property than the first sensing element. (Col. 5, lines 33-35, 40-42)

With respect to **Claim 7**: Fiddian-Green teaches a plurality of drain holes 74 or 274 on conduit 22 that are spaced along substantially the entire length of, and define, a drain portion. Such portion is configured to rest against a substantial length of tissue within the body through which a stomach or bladder may be aspirated. (Col. 6, lines 57-59, Col. 10, lines 32-34)

With respect to **Claim 8**: Fiddian-Green teaches lead 164 that outputs a voltage signal indicating a partial pressure of a gas, said voltage signal being fed to an analog-to-digital converter to a microcomputer 172 coupled to a CRT monitor 180 (display). (Col. 7, lines 66,67, Col. 8, line 2, 9-11, 24-27)

With respect to **Claim 9**: Fiddian-Green teaches a pump means (not shown) for continuous or intermittent aspiration of the aspirating medium that fills sample chamber 40 which is defined by an interior portion of balloon membrane 36 (inflatable compartment). (Fig. 1) (Col. 9, lines 41-46)

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With respect to **Claim 10**: Fiddian-Green teaches a separate exterior gas analyzing means (not shown) to determine the partial pressure of a gas from a sample of aspirating medium from sample chamber 40 (pressure monitor) (Col. 9, lines 46-51). The pressure monitor is thus in communication with the interior portion of the inflatable compartment.

Claims 11, 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiddian-Green ('064) in view of Wittes et al (U.S. Patent No. 3,680,562).

With respect to **Claims 11 and 15**: Fiddian-Green does not teach an anchor for stabilization of catheter 20 relative to tissue in a body cavity. Wittes teaches a catheter 32 comprising a sheath 38 bifurcated into half-tube wings 40,40' (flaps-claim 15) that serves as an anchoring means. Since Wittes teaches that catheter 32 is indwelling and designed to contact tissue, it would be obvious to one of ordinary skill in the art to modify the catheter 20 taught by Fiddian-Green to be fitted with a sheath having anchoring means as taught by Wittes.

With respect to **Claim 12**: Wittes teaches that bifurcated wings 40,40' are bent away from catheter tube 28 (i.e. extending from the outer side) and affixed to the skin to anchor catheter 32 via sutures after said tubing is implanted within a patient's bladder (thus being configured for insertion into tissue in the body).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fiddian-Green ('064) in view of Torre et al (U.S. Patent Application Publication No. 2002/0055757).

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With respect to **Claim 13**: Fiddian-Green does not teach a first loop extending from the surface of catheter tubing 22. Torre teaches an intragastric endoscope 10 having a loop on its surface for manipulation, deflation and/or removal of said endoscope. (§ 0016) Since Fiddian-Green is also teaching a device for gastro-intestinal use, the methods employed to manipulate each device by Fiddian-Green (balloon 36) and Torre (surface loop) are substantially equivalent and effect the same end result, i.e. manipulation, deflation and/or removal of an elongated conduit. Thus it would be obvious to one of ordinary skill in the art to substitute the balloon membrane taught by Fiddian-Green for manipulating, etc. an elongated conduit, with the loop taught by Torre with a reasonable expectation of success.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fiddian-Green ('064) in view of Schoolman (U.S. Patent No. 5,215,539).

With respect to **Claim 14**: Fiddian-Green does not teach that adhesive is disposed on the surface of catheter 20. Schoolman teaches a vacuum strip apparatus for surgical incisions comprising an elongate hollow strip 6 comprising a plurality of openings 28 (Col. 4, lines 61-66) and double-sided adhesive tape 41 on its engagement surface 39 for adhesion to a patient's skin 22. (Fig. 1) (Col. 5, lines 16,17,25-30) The methods employed to anchor each device by Fiddian-Green (balloon 36) and Schoolman (adhesive tape on a tissue engagement surface) are substantially equivalent and effect the same end result, i.e. anchoring an elongated conduit adjacent a desired tissue site in the body. Thus it would be obvious to one of ordinary skill in the art to substitute the balloon membrane taught by Fiddian-Green for anchoring an elongated conduit with the tape taught by Schoolman with a reasonable expectation of success.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

